

## **REMARKS**

The Office Action dated November 16, 2006 has been reviewed, and the comments of the U.S. Patent Office have been considered. Claims 1-37 are pending in this application. By this Amendment, claims 1, 35, and 37 are amended. The amendments are supported in the specification by at least paragraph [0005] and by Figs. 2-4.

Applicant appreciates the withdrawal of the finality of the July 17, 2006 Office Action.

Claims 1-17 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-17 of co-pending Application No. 10/726,960. The rejection is respectfully traversed.

The Office Action at page 2 asserts only that instant claims 1-17 are not patentably distinct from claims 1-17 of the '960 application because:

... the longitudinal length and the interior surface area are measurements of the same area of the balloon, both remaining unchanged. When the length is unchanged it is obvious that the surface area is unchanged, and vice versa.

Assuming, *arguendo*, that the rejection is based on a comparison of the scope of instant claims 1-17 to the scope of claims 1-17 of the '960 application, Applicant respectfully traverses the rejection because the scope of the claims, by itself, cannot support a double patenting rejection. *See* MPEP §804(II).

Applicant also traverses the rejection because the Office Action fails to establish a *prima facie* case of obviousness. The burden is on the Office to establish a *prima facie* case of obviousness as to why one of ordinary skill in the art would conclude that the inventions recited in instant claims 1-17 are an obvious variant of the invention recited in claims 1-17 of the '960 application. That is, there must be a suggestion or teaching in the '960 application that would motivate one of ordinary skill in the art to modify the invention recited in claims 1-17 of the '960 application in order to reach the invention recited in instant claims 1-17. Applicant respectfully submits that there is no suggestion or motivation provided by the Office, and the Office Action thus fails to establish a *prima facie* case of obviousness.

Furthermore, "length" and "area" have fundamentally different meanings and can not reasonably be viewed to be measurements of the same thing as asserted in the Office Action. The Office Action is incorrect where it asserts -- without support -- that "when the length is

unchanged it is obvious that the surface area is unchanged, and vice versa." The relationship between the length and the area of an object is not fixed as asserted in the Office Action. For example, in the case of a square-shaped area having a length of 2, a width of 2, and an area of 4, the length of 2 can remain unchanged and the width can be changed to 4, resulting in a change in area from 4 to 8.

Accordingly, the double patenting rejection should be withdrawn.

Claims 1-12, 15-29, and 32-37 stand rejected under 35 U.S.C. §102(b) over Hamlin (U.S. Pat. No. 5,270,086); and claims 13, 14, and 30-31 stand rejected under 35 U.S.C. §103(a) over Hamlin in view of Trotta (U.S. Pat. No. 5,290,306). The rejections are respectfully traversed.

Hamlin fails to show or describe a non-compliant medical balloon with a first fiber layer having fibers and a second fiber layer having fibers (as recited in independent claim 1), first and second layers each having at least one fiber therewithin (as recited in independent claim 35), or a first fiber layer including first fibers and a second fiber layer including second fibers (as recited in independent claim 37). Hamlin does not show or describe a balloon having fibers or a fiber layer. This is because Hamlin's balloon is fabricated from a parison 40 that was extruded from a melt to form the inner layer 48 and outer layer 56 of the Hamlin balloon. *See* Hamlin at col. 4, lines 46-49 and 64-68. Because the polymer material used to form parison 40 was melted prior to the extrusion process, any solid structures that may have been present in the polymer material (such as fibers) were melted into a liquid. Hamlin does not describe the reconstituted polymer (post melt) that forms layers 48 or 56 to contain any fibers or to form a fiber layer. Thus, even if the pre-melt nylon material described in Hamlin at col. 2, lines 31-54, was in the form of a fiber (as asserted in the Office Action at page 5), Hamlin does not show or describe that fiber structure to be present in the post-melt layers 48 and 56 of the Hamlin balloon.

Hamlin also fails to show or describe a non-compliant medical balloon with a first fiber layer having at least one fiber disposed along a longitudinal length of the non-compliant medical balloon (as recited in claim 1), a first layer at least one fiber having a length corresponding to a predetermined longitudinal length of the balloon (as recited in claim 35), and a first fiber layer including first fibers and at least one fiber of the first fibers disposed along a predetermined longitudinal length of the balloon (as recited in claim 37). As stated above, Hamlin does not show or describe a fiber or a fiber layer and thus could not show or describe a balloon having the recited "at least one fiber" because Hamlin's layers 48 and 56 are formed from a melt. *See*

Hamlin at col. 4, lines 46-49 and 64-68. Also, Hamlin does not show or describe an arrangement of a fiber within layers 48 and 56, a fiber disposed along a longitudinal length of the Hamlin balloon, or a fiber having a length corresponding to a predetermined longitudinal length of the Hamlin balloon.

Hamlin also fails to show or describe a non-compliant medical balloon with a first fiber layer and a second fiber layer with the second fiber layer disposed over the first fiber layer such that the fibers of the first fiber layer and the fibers of the second fiber layer form an angle (as recited in claim 1), a first layer at least one fiber being oriented at an angle with respect to a second layer at least one fiber (as recited in claim 35), and a second fiber layer being positioned over a first fiber layer such that the fibers of the first and second directions form an angle with respect to each other (as recited in claim 37). The Office Action at page 3 asserts that Fig. 5 shows fibers of layers 48 and 56 forming an angle relative to each other, but those figures do not show fibers or an angle formed between fibers. To the extent the Office Action interprets the cross hatching of Hamlin's Fig. 5 to disclose an angle, that interpretation is contrary to 37 C.F.R. §1.84(h)(3) and MPEP §608.02(IX).

Also, the Office Action improperly relies on hindsight reasoning. The Office Action at page 3 twice asserts that "with the correct combination of materials" the Hamlin balloon would possess certain features recited in claim 1. This basis for the rejection is improper hindsight reasoning because the only source for the asserted "correct combination of materials" is Applicant's own disclosure.

Furthermore, with regard to claims 35-37, the Office Action fails to set forth a proper rejection because it does not explain where Hamlin shows or describes a balloon having a predetermined longitudinal length (as recited in claims 35-37), a balloon layer with a tensile strength and orientation (as recited in claims 35-36), a balloon having a first fiber layer including first fibers which are parallel and whose orientations and mechanical properties impart a tensile strength of said first layer in a first direction (as recited in claim 37), or a balloon having a second fiber layer including second fibers which are parallel whose orientations and mechanical properties impart a tensile strength of said second layer in a second direction (as recited in claim 37).

In addition to the above, the applied references fail to show or describe the features recited in dependent claims 2-34.

With regard to claims 2 and 19, Hamlin fails to show or describe the recited inelastic fibers because the citation relied upon in the Office Action (Hamlin at col. 2, lines 31-68) provides no description regarding the elasticity of fibers and provides only a list of pre-melt materials that could be used to form the Hamlin balloon, and none of the materials listed are described to be inelastic fibers, and the layers 48 and 56 of the Hamlin balloon are not described to include inelastic fibers.

With regard to claims 3, 5, 20, and 22, Hamlin fails to show or describe the recited parallel fibers because col. 3, lines 1-8, (the citation relied upon in the Office Action) provides only a non-specific description regarding the possible combining of materials, and there is no description regarding parallel fibers.

With regard to claims 4 and 21, Hamlin fails to show describe a balloon having at least four layers that include a first fiber layer, a second fiber layer, a binding layer, and an adhesive layer. The Office Action bases the rejection of claims 4 and 21 on Hamlin at col. 2, lines 12-30, but Hamlin's "bonding inner layer" at col. 2, line 14, is the same "bonding layer" referred to at col. 2, line 55, that was already cited to and relied upon in the rejection of claim 1 (in regard to the recited "binding layer"). Hamlin thus fails to show or describe an adhesive layer and a binding layer because Hamlin describes only a single "bonding layer."

With regard to claims 6, 8, 9, 16, 18, 23, 25, 26, and 33, Hamlin fails to show or describe the recited angles or arrangements because Hamlin at Figs. 4 and 5 (the citation relied upon in the Office Action) does not show fibers, fiber layers, or the recited angles or arrangements.

With regard to claims 7 and 24, Hamlin fails to show or describe the recited features and the Office Action relies on hindsight reasoning where it asserts that "with the correct combination of materials" the Hamlin balloon would possess the recited features. The rejections are improper hindsight reasoning because the only source for the asserted "correct combination of materials" is Applicant's own disclosure.

With regard to claims 10-12 and 27-29, Hamlin fails to show or describe the recited coatings. The Office Action bases the rejections of these claims on Hamlin at col. 2, lines 31-68, but the materials described in that section of Hamlin are not coatings but, instead, raw materials to be used in the melt extruded by Hamlin's blow mold 42.

With regard to claims 13-14 and 30-31, Trotta fails to show or describe fibers and thus fails to remedy the deficiencies of Hamlin. Furthermore, the Office Action relies on Trotta for

its description of a thickness of a hydrogel layer 24, which is not a thickness of a fiber or fiber layer. *See* Trotta at col. 4, lines 55-59.

With regard to claims 15 and 32, the Office Action fails to set forth any basis for the rejection of this claim based on Hamlin.

With regard to claims 17 and 34, Hamlin fails to show or describe a third fiber layer. The Office Action relies on Hamlin at col. 2, lines 12-30, and appears to assert that Hamlin's "bonding layer" corresponds to the recited third fiber layer. However, this interpretation of Hamlin is inconsistent because the Office Action in the rejection of claim 1 already correlates Hamlin's "bonding layer" with the recited "binding layer" and, thus, Hamlin's "bonding layer" can not also be the recited third fiber layer. Furthermore, Hamlin's "bonding layer" is not described as having fibers or otherwise being a fiber layer.

For the foregoing reasons, the applied references alone or in combination fail to show, describe, teach, or suggest all of the features recited in the independent claims or the dependent claims thereof. It is respectfully requested that the rejections be withdrawn.

In addition to the above, the Office Action at page 5 improperly relies on information purportedly obtained from "wikipedia.com" to support the assertion that it is common knowledge that the materials listed in Hamlin exist only in the form of fibers. This purported factual assertion is traversed by Applicant because the materials listed in Hamlin at col. 2, lines 31-54, are described as being able to take the form of a melt (see Hamlin at col. 4, lines 46-49) and thus are not exclusively limited to the form of a fiber as asserted in the Office Action. MPEP §2144.03(C) requires the Office Action's assertion of common knowledge to be supported by documentary evidence, and any reliance on wikipedia.com can not satisfy that requirement. The wikipedia.com web site expressly states that the information contained therein is not reliable and subject to revision at any time. *See* [http://en.wikipedia.org/wiki/Main\\_Page](http://en.wikipedia.org/wiki/Main_Page) (described as the "the free encyclopedia that anyone can edit."); *see also* [http://en.wikipedia.org/wiki/Wikipedia:General\\_disclaimer](http://en.wikipedia.org/wiki/Wikipedia:General_disclaimer) ("Wikipedia cannot guarantee the validity of the information found here. The content of any given article may recently have been changed, vandalized or altered by someone whose opinion does not correspond with the state of knowledge in the relevant fields.") Furthermore, a web site is not the "documentary evidence" required by MPEP §2144.03(C), and not contemporaneous with the filing date of the application.

Accordingly, pursuant to MPEP §2144.03(C), the Office Action's assertion of common knowledge should be withdrawn.

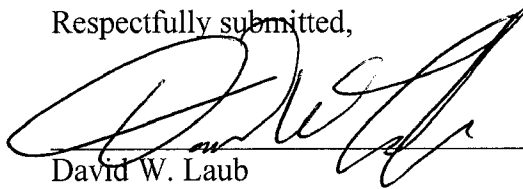
**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this Application and the prompt allowance of at least claims 1-37.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,



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